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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,040	06/06/2001	James Robl	P 280633 23523-0008	8078

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1632

DATE MAILED: 09/10/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,040

Applicant(s)

ROBL ET AL.

Examiner

Anne M Wehbé

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

DETAILED ACTION

Applicant's response received on 6/27/02 has been entered. Claims 1-35 have been canceled. New claims 36-87 have been entered. Claims 36-87 are currently pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

Claim Rejections - 35 USC § 101

The rejections of claims 1-35 under 35 U.S.C. 101 have been withdrawn in view of applicant's cancellation of the claims.

In regards to applicant's arguments regarding the applicability of the previous grounds of rejection to applicant's new claims, please note that new claims 36-87 have not been rejected under 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

Art Unit: 1632

The rejection of claims 1-35 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of applicant's cancellation of the claims. Please note that applicant's new claims do not recite or claim human embryonic stem cells or stem-like cells.

The rejection of claims 1-35 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's cancellation of the claims.

Claim Rejections - 35 USC § 102

The rejection of claims 18-25 under 35 U.S.C. 102(e) as being anticipated by Tsukamoto et al. is withdrawn in view of applicant's cancellation of the claims.

The rejection of claims 18-23 under 35 U.S.C. 102(a) as being anticipated by Granerus et al. is withdrawn in view of applicant's cancellation of the claims.

The rejection of claims 18-25 under 35 U.S.C. 102(b) as being anticipated by Yamane is withdrawn in view of applicant's cancellation of the claims.

Claim Rejections - 35 USC § 103

Art Unit: 1632

The rejection of canceled claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Wolfe et al. in view of Collas et al. is maintained over new claims 36-87. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant states that neither Wolfe et al. nor Collas et al. teach that a blastocyst could be produced by cross-species nuclear transfer using a differentiated mammalian cell as the nuclear donor cell. Applicant's arguments however focus on the teachings of Wolfe et al. and do not address the teachings of Collas et al. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The rejection of record is based on the combined teachings of Wolf et al. and Collas et al. It is noted, that the test for combining references is not what the individual references themselves suggest, but rather what the combination of disclosures taken as a whole would have suggested to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In regards to applicant's arguments that Wolfe et al. does not teach using a differentiated cell as the nuclear donor cell, the prior action clearly stated that the Collas supplements Wolfe et al. by teaching the use of differentiated nuclei for nuclear transfer resulting in the generation of blastocysts. In particular, Collas et al. teaches that both differentiated somatic granulosa cell nuclei and differentiated inner cell mass nuclei can be transferred to enucleated oocytes and

Art Unit: 1632

developed into blastocysts (Collas et al., page 264). Collas also teaches that nuclei from differentiated mouse thymocytes can be used as donor nuclei in nuclear transfer methods for the production of blastocysts (Collas et al, page 266, column 1). Thus, Collas et al. concludes that a variety of differentiated mammalian cell types can be used in nuclear transfer to generate blastocysts (Collas et al., page 266, column 1). Accordingly, in view of the collective cited prior art and in particular the successful use of differentiated nuclei to produce blastocysts as taught by Collas et al., it would have been *prima facie* obvious for one of ordinary skill in the art to select human differentiated cell nuclei and bovine oocytes for use in cross-species nuclear transfer with a reasonable expectation of producing at least one nuclear transfer unit which is capable of developing to the embryonic blastocyst stage of development.

In the absence of a showing of unexpected results by Applicants relating to the production of nuclear transfer units or to the differentiation capacity of the NT units of the instant invention, the cited prior art provides sufficient motivation to select cross-species differentiated mammalian cell nuclei and oocytes for use in nuclear transfer methodology with a reasonable expectation of producing at least one nuclear transfer unit of which is capable of developing into a blastocyst. Please note that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. § 103, all that is required is a **reasonable** expectation of success. See In re O'Farrell, 7 USPQ2d 1673 (CAFC 1988).

No claim is allowed.

Art Unit: 1632

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

**ANNE M. WEHBE' PH.D
PRIMARY EXAMINER**

